



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION
Southwest Region/Denver District
Denver Federal Center, Bldg. 20
P.O. Box 25087, Denver, CO 80225
Telephone: (303) 236-3000

December 7, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Ayla Hightower
Ayla's Hair, Skin, and Fine Fragrances
1513 East 10th Street
Alamogordo, NM 88310

Ref. # - DEN-00-03

WARNING LETTER

Dear Ms. Hightower:

This letter is in reference to the promotion, marketing, and distribution of your product "Ayla's Formula 777 Skin Creme."

The product is marketed and promoted through an Internet web site (www.aylas.com) and through printed promotional literature displayed with the product. Included in your Internet web site are such claims as:

- "Here are some new, very recent testimonials: Clears up Skin Tumors!; ... A very grateful regular user from Las Cruces, New Mexico, raves how it healed her 12 year old genital Herpes in two days; ... scars from Shingles over the temple, nothing ever made it go away until she applied anointed Formula 777 creme; ... had bad congestion, and coughing, and coughing ... next day her condition was much better; ... sty on upper eyelid cleared in two days ...; I had been having severe constipation, discomfort, and pain in my bowels and lower abdomen. I had not been able to pass for 5 days. ... Within five minutes my bowels cleared ...; Formula 777 Crème and Stroke Patient ... I had a stroke 3 weeks ago that paralyzed my left side ... my fingers started moving on my left hand! ... Now I have a grip on that hand..."

Included among the claims found in your labeling (promotional literature consisting of copies of paid advertising under the headlines of “Business of the Week” displayed with the product) are such claims as:

- “Seems to help with: Acne (adult, cystic, keloid) ... Arthritis (feels normal); Athlete’s Foot ... Bedsores ... Bleeding Gums, Blemishes, Red Blotches ... Constipation ... Yeast Infection ... Eczema ... Fungus (when others Don’t help) ... Hemorrhoids ... Psoriasis (unbelievable Ttestimonials (sic)) ... Ringworm ... Skin Ulcers, Skin Cancer (join the result Getters) ... Skin Irritations ... Toothache ...”
- “The new very recent testimonials, such as how it got rid of Skin Tumors ... healed her 12 year old genital herpes in two days ... solved her poison ivy problem ... scars from Shingles ... bad Congestion and coughing, and coughing ... sty on upper eyelid cleared ...”;
- “One of my relatives had varicose veins that bled to touch, they were so close to the skin they would burst open. I gave him your Formula 777 Creme which he used and it cleared right up.”
- “My mom is in the hospital with lung congestion due to heart failure - Her legs were swollen & itching in spots. I applied 777 creme ... That was yesterday & today the swelling in her legs was gone ...”

Based on the claims made for the product and its intended uses, the product is a drug [Section 201(g) of the Federal Food, Drug, and Cosmetics Act (the Act)]. It is also a new drug [Section 201(p) of the Act] and may not be legally marketed in the United States without an approved New Drug Application (section 505).

The drug is also misbranded because the labeling fails to bear adequate directions for use [section 502(f)(1)] and is false and misleading as it suggests that the product is safe and effective for the intended uses when this has not been established [section 502(a)].

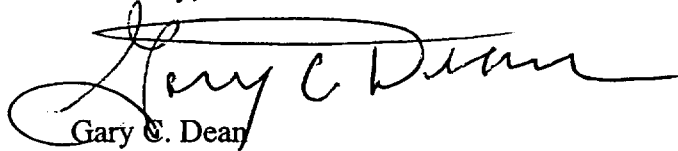
This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Ms. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

Sincerely,



Gary C. Dear
Director, Denver District

**REVIEWED
NOTHING PURGED**